



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-0957]

Compliance Policy Guides Sec. 335.500; Sec. 310.200; Sec. 393.100; Sec. 398.425; Sec. 394.500; Sec. 300.750; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of six compliance policy guides (CPG). The Agency is taking this action because the CPGs identified in this notice contain information that is either duplicative of other information the Agency has published or no longer reflects the Agency's current thinking.

DATES: The withdrawal is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993-0002, 301-796-6353.

SUPPLEMENTARY INFORMATION:

After careful review of CPGs related to device products, FDA has identified the following six CPGs, that contain information that is either duplicative or no longer reflects the Agency's current thinking.

FDA originally issued CPG Sec. 335.500, "Razor Blades, Manicuring Instruments – Not Considered Devices Under 201(h)" (CPG Sec. 335.500) in April 1976. The CPG was revised periodically but has not been revised since March 1995. Given the time that has passed since the last revision of CPG Sec. 335.500, upon further review, FDA has determined that while the CPG

still reflects the Agency's current thinking, it is no longer needed because it appears to be seldomly accessed.

CPG Sec. 310.200, "Sphygmomanometers--Rx Legend" (CPG Sec. 310.200) was originally issued in January 1973. The CPG was revised periodically but has not been revised since September 1987. Since CPG Sec. 310.200 was last updated, many of these products have been cleared to be sold over the counter and therefore, the policy contained in this CPG is obsolete and no longer needed.

CPG Sec. 393.100, "Enforcement Policy for Certain Laser Light Shows, Displays, and/or Devices. (21 CFR 1040.10 and 1040.11)" (CPG Sec 393.100) was originally issued in October 1980. The CPG was revised periodically but has not been revised since March 2005. Since CPG Sec. 393.100 was last revised, the policies regarding these products have been updated and additional resources have been made available to the public regarding these products, including in four laser notice guidance documents.¹ The change in policies and the availability of additional resources has resulted in the information contained within CPG Sec. 393.100 to be duplicative and outdated.

CPG Sec. 398.425, "Override of Positive Beam Limitation--21 CFR 1020.31(g)(5)" (CPG Sec. 398.425) was originally issued in October 1980. The CPG was revised periodically but has not been revised since March 2005. Given the time that has passed since the last revision of CPG Sec. 398.425, upon further review, FDA has determined that the CPG provides duplicative information to what is provided in 21 CFR 1020.31(g)(5).

CPG Sec. 394.500, "Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation during Design Development" (CPG Sec. 394.500) was originally issued in March 1984. The CPG was revised periodically but has not been revised since July 2004. Given the time that has passed since the last revision of CPG Sec.

¹ See <https://www.fda.gov/radiation-emitting-products/home-business-and-entertainment-products/laser-light-shows>.

394.500, upon further review, FDA has determined that the CPG contains outdated information and references.

Finally, CPG Sec. 300.750, “Class III Devices Subject to 515(b) Requirements” (CPG Sec. 300.750) was originally issued in October 1990. The CPG was revised periodically but has not been revised since July 2005. Since CPG Sec. 300.750 was last revised, FDA has completed the actions for the preamendment class III devices discussed in the CPG to either reclassify them into class I, or II, or, if retaining the device in class III, calling for PMAs;² as such, the CPG is obsolete.

Therefore, after careful review, FDA is withdrawing CPG Sec. 335.500, CPG Sec. 310.200, 393.100, CPG Sec. 398.425, CPG Sec. 394.500, and CPG Sec. 300.750 in their entirety because the CPGs are either obsolete or contain duplicative information.

Dated: April 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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² See <https://www.fda.gov/about-fda/cdrh-transparency/515-program-initiative> and <https://www.fda.gov/about-fda/cdrh-transparency/515-project-status>.